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10/594,839	09/28/2006	Motoaki Kamachi	Q80934	3708
23373. 7599 10/13/2009 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W.			EXAMINER	
			GOON, SCARLETT Y	
SUITE 800 WASHINGTON, DC 20037		ART UNIT	PAPER NUMBER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

#### Application No. Applicant(s) 10/594,839 KAMACHI ET AL. Office Action Summary Examiner Art Unit SCARLETT GOON 1623 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  Extensions of time may be available under the provisions of 37 CF8 1 1360, in no event, however, may a reply be timely filed after SIX (6) MONTH'S from the mailing date of this communication.  If NO profit or reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTH'S from the making date of this communication.  Any reply received by the Officia later than three months after the making date of this communication, even if timely filed, may reduce any earned pattern term adjustments. See 37 CF8 1.704(8).
Status
1) Responsive to communication(s) filed on 30 July 2009.  2a) This action is FINAL. 2b) This action is non-final.  3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.
Disposition of Claims
4) ⊠ Claim(s) 1.4-7.10.11.14-16 and 19-21 is/are pending in the application.  4a) Of the above claim(s) is/are withdrawn from consideration.  5) □ Claim(s) is/are allowed.  6) ⊠ Claim(s) 1.4-7.10.11.14-16 and 19-21 is/are rejected.  7) □ Claim(s) is/are objected to.  8) □ Claim(s) are subject to restriction and/or election requirement.  Application Papers
9) The specification is objected to by the Examiner.
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.
Priority under 35 U.S.C. § 119
12) △ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) △ All b) ☐ Some * c) ☐ None of:  1. ☐ Certified copies of the priority documents have been received.  2. ☐ Certified copies of the priority documents have been received in Application No  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.

3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date \_\_\_\_\_ PTOL-326 (Rev. 08-06)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

1) Notice of References Cited (PTO-892)

Attachment(s)

Art Unit: 1623

#### DETAILED ACTION

### Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 30 July 2009 has been entered.

This Office Action is in response to Applicants' Amendment and Remarks filed on 30 July 2009 in which claims 2, 3, 8, 9, 12, 13, 17 and 18 were previously cancelled, and new claim 21 is added.

Claims 1, 4-7, 10, 11, 14-16 and 19-21 are pending in the instant application and are examined on its merits herein.

# Priority

This application is a National Stage entry of PCT/JP05/06411 filed on 25 March 2005 and claims priority to Japan foreign application 2004-105929 filed on 31 March 2004 and U.S. provisional application no. 60/560607 filed on 9 April 2004. A certified copy of the foreign priority document in Japanese has been received. No English translation has been received.

# Rejections Withdrawn

The rejection of claims 1, 4-7, 10, 11, 14-16, 19 and 20 (incorrectly indicated as 1-20 in the previous Action) under 35 USC § 103(a), as being unpatentable over JP2003-252904 by Kakuchi et al., in view of US Patent No. 6,197,319 B1 to Wang et al., is withdrawn because the Wang '319 patent only teaches the use of anionic polysaccharides in cosmetic compositions. Since the multi-branched polysaccharides disclosed by Kakuchi et al. are not anionic, one of ordinary skill in the art would have no motivation to substitute the anionic polysaccharides disclosed in the Wang '319 patent with the neutral polysaccharides disclosed by Kakuchi et al.

These rejections have been withdrawn.

The following are new grounds of rejections.

### Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy of policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harasament by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s). See, e.g., in re Jenger, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1985); In re Van Ormun, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a ionit research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Art Unit: 1623

Claims 1, 4-7, 10, 11, 14-16, 19 and 20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 8-10, 14 and 18-22 of U.S. copending application no. 11/088,794, in view of JP2003-252904 by Kakuchi *et al.* (IDS dated 28 September 2006, machine translation).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application is drawn to a polysaccharide/functional compound complex wherein the multi-branched polysaccharide is composed of a saccharide structural unit, and at least one of the hydroxyl groups of the multi-branched polysaccharide is replaced by OR, wherein R represents a hydrogen atom, a hydrocarbon having 1-30 carbon atoms, or a hydrocarbon having 1-30 carbon atoms and hetero atoms (claim 1). The multi-branched polysaccharide is a polymer composed of a monomer or an anhydrosaccharide (claim 2). The anhydrosaccharide is selected from 1,6-anhydrosaccharide, 1,4-anhydrosaccharide, 1,3-anhydrosaccharide, 1,2-anhydrosaccharide, and 5,6-anhydrosaccharide (claim 3). The degree of branching of the multi-branched polysaccharide is 0.05 to 1.00 (claims 4 and 9). The copending application is also drawn to an external preparation or cosmetic that comprises 0.01 to 100% by mass of the polysaccharide/functional compound complex (claims 18 and 19).

The claims of the instant application are drawn to an external preparation of cosmetic comprising a multi-branched polysaccharide with multi-branched polysaccharide skeletons consisting of anhydrosaccharides wherein at least one of the hydroxyl groups of the multi-branched polysaccharide skeleton is substituted by OR

Art Unit: 1623

wherein R represents a hydrogen atom, a hydrocarbon having 1-30 carbon groups, or a hydrocarbon having 1-30 carbon groups and a hetero atom (claim 1). The branching degree of the multi-branched polysaccharide is 0.05 to 1.00 (claim 5). The external preparation or cosmetic comprises 0.1 to 80 mass % of the multi-branched polysaccharide (claims 6, 10 and 11).

The copending application does not disclose specific anhydrosaccharides other than the location of the anhydro moiety. Kakuchi *et al.* disclose multi-branching polysaccharides wherein the anhydrosugars can be 1,6-anhydro-β-D-glucopyranose, 1,6-anhydro-β-D-galactopyranose, 1,6-anhydro-β-D-galactopyranose, 1,6-anhydro-β-D-galactopyranose, 1,6-anhydro-β-D-galactopyranose, 1,4-anhydro-α-D-glucopyranose, 1,4-anhydro-α-L-arabinopyranose, 1,4-anhydro-α-D-glucopyranose, 1,3-anhydro-β-D-mannopyranose, 1,2-anhydro-β-D-mannopyranose, 1,2-anhydro-α-D-glucopyranose, 1,2-anhydro-β-D-mannopyranose, and 5,6-anhydro-α-D-glucopyranose (p. 4 and 5).

Thus, the instant claims 1, 4-7, 10, 11, 14-16, 19 and 20 are seen to be obvious over claims 1-4, 8-10, 14, 18-22 of U.S. copending application no. 11/088,794 in view of JP2003-252904 by Kakuchi *et al.* (IDS dated 28 September 2006, machine translation).

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1623

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 5, 7, 14 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by JP2003-252904 by Kakuchi *et al.* (IDS dated 28 September 2006, machine translation).

Kakuchi et al. teach a method for manufacturing multi-branching polysaccharides which are obtained by polymerization in the presence of a cation or anion initiator and an anhydrosugar (p. 4, section 0003). The multi-branching polysaccharides are useful as a thickener in a biocompatible gel or a medically-based material (p. 3, section 0001). The anhydrosugars can be a 1,6-anhydrosugar, a 1,4-anhydrosugar, a 1,3anhydrosugar, or a 1,2-anhydrosugar (p. 4). More specifically, the anhydrosugars can be 1,6-anhydro-β-D-glucopyranose, 1,6-anhydro-β-D-mannopyranose, 1,6-anhydro-β-Dgalactopyranose, 1,6-anhydro-β-D-altropyranose, 1,4-anhydro-α-D-xylopyranose, 1,4anhydro-α-L-arabinopyranose, 1,4-anhydro-α-D-lyxopyranose, 1,3-anhydro-β-Dglucopyranose, 1,3-anhydro-β-p-mannopyranose, 1,2-anhydro-α-p-glucopyranose, 1,2anhydro- $\beta$ -D-mannopyranose, and 5,6-anhydro- $\alpha$ -D-glucopyranose (p. 4 and 5). The hydroxyl groups of the anhydrosugar may be substituted with OR wherein R is a hydrogen atom or a hydrocarbon having 1-30 carbon atoms (p. 3, claim 4). The degree of branching of the multi-branching polysaccharide is between 0.05 to 1.00 (p. 5, section 0005). The water-soluble multi-branching polysaccharide can be synthesized in high reproducibility in large quantities to enable their use as a functional material on an industrial scale (p. 7, section 0010). Furthermore, unlike natural branching

Art Unit: 1623

polysaccharides, such as amylopectin, the molecular weight and degree of branching can be controlled (p. 7, section 0010).

It is noted that although Kakuchi et al. teach that the multi-branching polysaccharide is useful as a thickener in a biocompatible gel or as a medically-based material, the reference does not explicitly teach that the polysaccharide is used in an external preparation for the skin or as a cosmetic. However, the recitations "external preparation for the skin" and "cosmetic" are considered to be an "intended use" of the composition, and is therefore not given any patentable weight. Applicants are requested to note that the "intended use" of a composition will not further limit the claims drawn to a composition or product, so long as the prior art discloses the same composition comprising the same ingredients in an effective amount, as the instantly claimed. See, e.g., Ex parte Masham, 2 USPQ2d 1647 (1987) and In re Hack 114, USPQ 161.

Thus, the multi-branching polysaccharides disclosed by Kakuchi *et al.* anticipate claims 1, 4, 5, 7, 14 and 15.

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Art Unit: 1623

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

# Section [0001]

Claims 6, 10, 11, 16 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP2003-252904 by Kakuchi *et al.* (IDS dated 28 September 2006, machine translation) as applied to claims 1, 4, 5, 7, 14 and 15, further in view of U.S. Patent No. 5,900,241 to Roulier *et al.* (herein referred to as the '241 patent; PTO-892, Ref. A).

Art Unit: 1623

The teachings of Kakuchi et al. were as disclosed above in the claim rejections under 35 USC § 102.

The teachings of Kakuchi *et al.* differ from that of the instantly claimed invention in that Kakuchi *et al.* do not teach that the multi-branched polysaccharide is present in the composition in the range from 0.1 to 80%.

The Roulier '241 patent teaches expanded solid compositions whose matrix contains an alveolar network made from a natural product or from a derivative of a natural product capable of being expanded, as well as cosmetic and dermatological compositions containing the expanded solid compositions. Natural products and derivatives thereof that are capable of being expanded and therefore preferably employed as the matrix include vegetable proteins, animal proteins, proteins derived from dairy products, gelatin, amylose and/or amylopectin, and starch-rich products containing amylose and/or amylopectin (column 2, lines 45-52). The expanded solid compositions are generally stored in the dry state, but is easily rehydratable after immersion in an aqueous medium in order to be used in make-up formulations such as foundations, or formulations for care or hygiene, such as creams, milks, bubble baths, gels and shampoos (column 2, lines 12-17). The matrix containing the alveolar network formed from a natural product or from a derivative of a natural product capable of being expanded is present in the compositions in a proportion ranging from 25 to 98% by weight relative to the weight of the composition (column 5, lines 35-40). Example 1 discloses dry shampoo in the form of pellets which comprise 35% by weight of wheat

flour and 35% by weight of corn starch, both of which are composed of amylose and amylopectin polysaccharides (column 8, lines 15-25).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Kakuchi et al., concerning a method for manufacturing multi-branched polysaccharides, with the teachings of the Roulier '241 patent, regarding expanded solid compositions whose matrix contains an alveolar network made from a natural product or from a derivative of a natural product capable of being expanded for use in cosmetic and dermatological compositions. Since Kakuchi et al, teach that the multi-branching polysaccharides are useful as a thickener in a biocompatible gel or a medically-based material, and further teach that the multibranching polysaccharides are more advantageous over natural branching polysaccharides, such as amylopectin, because the molecular weight and degree of branching of the disclosed multi-branching polysaccharides can be controlled, one would have been motivated to combine the teachings and substitute the amylopectin or starch polysaccharides of the shampoo composition disclosed in the Roulier '241 patent with the multi-branching polysaccharides disclosed by Kakuchi et al., in order to receive the expected benefit, as suggested by Kakuchi et al., that the water-soluble multibranching polysaccharide can be synthesized in high reproducibility in large quantities to enable their use as a functional material on an industrial scale (p. 7, section 0010). and that the molecular weight and degree of branching can be controlled (p. 7, section 0010), thereby providing homogeneous polysaccharide structures. One of ordinary skill in the art would view that the ability to control the molecular weight and degree of

branching of the multi-branched polysaccharide present in a dermatological product or cosmetic is advantageous because it would likely yield more reproducible properties for the cosmetic composition, as compared to the heterogeneity observed with naturally branched polysaccharides, such as amylopectin. Furthermore, as the multi-branched polysaccharides disclosed by Kakuchi et al. have the same properties as that desired for the expanded solid compositions disclosed in the Roulier '241 patent, namely that the product is capable of being expanded, similar to the function of a thickener, one of ordinary skill in the art would reasonably expect the substitution to give a predictable result of being an expandable solid composition that can be used in cosmetic and dermatological applications.

Thus, the claimed invention as a whole is *prima facie* obvious over the combined teachings of the prior art.

The following rejection of record in the previous Office Action is maintained, with a slight modification to correct for canceled claims and to incorporate the rejection of new claim 21.

# Section [0002]

Claims 1, 4-7, 10, 11, 14-16 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP2003-252904 by Kakuchi et al. (IDS dated 28 September

Art Unit: 1623

2006, machine translation) in view of PG Pub No. US 2002/00065328 A1 by Dederen et al. (of record).

The teachings of Kakuchi et al. were as disclosed above in the claim rejections under 35 USC § 102.

Although Kakuchi et al. teach that the multi-branching polysaccharide is useful as a thickener in a biocompatible gel or as a medically-based material, the reference does not explicitly teach that the compound is used as an external preparation for the skin, or as a cosmetic. Furthermore, it is noted that Kakuchi et al. do not explicitly teach the limitations of claims 10 and 11, wherein the multi-branched polysaccharide is present in 0.1 to 80%.

Dederen et al. teach a personal care or cosmetic oil in water emulsion that includes an oil emulsifier and a combination of a Xanthan polysaccharide and a polyglucomannan polysaccharide to provide enhanced stability. Personal care products include cosmetic skin creams, lotion and milks (paragraphs 0002 and 0009). Polyglucomannan typically has a random glucose/mannose backbone, typically at a molar ratio of glucose to mannose in the range of about 1:1.5 to about 1:3, with various acetylated groups (paragraph 0011). The molecular weight of useful polyglucomannans can vary within a typical range of from about 2x10<sup>5</sup> to about 2x10<sup>6</sup> (paragraph 0011). The amount of polysaccharide stabilizer used is from about 0.02% to about 0.5% by weight of the emulsion (paragraph 0018).

As such, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Kakuchi et al., concerning a method for

Art Unit: 1623

manufacturing multi-branching polysaccharides, with the teachings of Dederen et al., regarding a personal care or cosmetic oil in water emulsion that includes an oil emulsifier and a combination of a Xanthan polysaccharide and a polyglucomannan polysaccharide to provide enhanced stability. One would have been motivated to combine the teachings in order to receive the expected benefit, as suggested by Kakuchi et al., that the water-soluble multi-branching polysaccharide can be synthesized in high reproducibility in large quantities to enable their use as a functional material on an industrial scale (p. 7, section 0010), and that the molecular weight and degree of branching can be controlled (p. 7, section 0010), thereby providing homogeneous polysaccharide structures. Additionally, as Dederen et al. teach that polyglucomannan is highly heterogeneous, like most natural polysaccharides, one of ordinary skill in the art would be motivated to substitute the polysaccharides described by Dederen et al. with those described by Kakuchi et al., in the preparation of a cosmetic composition, as the synthetic polysaccharides described by Kakuchi et al. are likely to yield more reproducible properties for the cosmetic composition than heterogenous natural polysaccharides.

Thus, the claimed invention as a whole is *prima facie* obvious over the combined teachings of the prior art.

### Response to Arguments

Applicant's arguments filed 30 July 2009 with respect to the rejection of claims 1, 4-7, 10, 11, 14-16 and 19-21 made under 35 USC § 103(a) as being unpatentable over

Kakuchi et al., in view of PG Pub No. US 2002/00065328 A1 by Dederen et al., have been fully considered but they are not persuasive.

Applicants argue that multi-branched polysaccharides are completely different from linear polysaccharides in terms of structure and physical properties, and are not used in a field where linear polysaccharides are applied. This argument is not persuasive because the new rejection in section [0001] above indicates that Roulier et al. teach the use of amylose (a linear polysaccharide) and/or amylopectin (a multi-branched polysaccharide) in cosmetic or dermatological applications. Thus, contrary to Applicants' argument, multi-branched polysaccharides have been shown to be used in the same fields of endeavor as linear polysaccharides.

Applicants further argue that multi-branched polysaccharide greatly differs from a linear polysaccharide in that it does not increase the viscosity of a cosmetic even if it is added in a large amount. Applicants further submit that polysaccharides are not typically added to increase the viscosity of cosmetic preparations. In view of this statement by Applicant, it is unclear why Applicants previously argued that the difference in viscosity between linear polysaccharides and multi-branched polysaccharides would not motivate one to substitute the polysaccharides of Dederen et al. with the multi-branched polysaccharides taught by Kakuchi et al. Based on Applicants' statement, the difference in viscosity between linear and multi-branched polysaccharides would be of no concern to an ordinarily skilled artisan when preparing cosmetics using polysaccharides. It is therefore maintained that the teachings of the Kakuchi et al., that the water-soluble multi-branching polysaccharides can be

synthesized in high reproducibility in large quantities to enable their use as a functional material on an industrial scale, is sufficient motivation for one to combine the teachings of Kakuchi *et al.* with Dederen *et al.* to arrive at the instantly claimed invention.

The rejections are still deemed proper and therefore maintained.

#### Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SCARLETT GOON whose telephone number is 571-270-5241. The examiner can normally be reached on Mon - Thu 7:00 am - 4 pm and every other Fri 7:00 am - 12 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/594,839 Page 16

Art Unit: 1623

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shaojia Anna Jiang/ Supervisory Patent Examiner, Art Unit 1623 SCARLETT GOON Examiner Art Unit 1623